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No. 07-192

IN THE

Supreme Court of the United States

ADVANCED CARDIAC SOLUTIONS, P.C., ET AL.,
Petitioners,

v.

CENTRAL ADMIXTURE PHARMACY SERVICES, INC., ET AL.,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

While performing work under a funding agreement with the National Institutes of Health ("NIH"), Dr. Buckberg discovered solutions of immense importance to heart surgery. The federal government expressly decided to allow Dr. Buckberg to retain all patent rights. The question presented is whether, pursuant to 35 U.S.C. § 202, Dr. Buckberg is automatically stripped of title to the patent on his invention – thereby negating the rights of his exclusive licensee – simply because, many years ago, he inadvertently did not submit to the NIH an executed copy of a government license, a license that the NIH can obtain at any time.

STATEMENT OF PARTIES AND RULE 29.6 DISCLOSURE

Petitioners, who were defendants-appellants below, are Advanced Cardiac Solutions, P.C., and Charles Wall.

Respondents, who were plaintiffs-appellees below, are Central Admixture Pharmacy Services, Inc., and Dr. Gerald D. Buckberg. Respondent Central Admixture Pharmacy Services, Inc., is the wholly owned subsidiary of B. Braun Medical, Inc.

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BRIEF OF RESPONDENTS IN OPPOSITION

The Federal Circuit has issued a correct decision that is consistent with the precedent of this Court and decisions of other circuits. The petition should be denied.

STATEMENT

1. The Bayh-Dole Act, 35 U.S.C. §§ 200-212, governs the patent rights in inventions made with federal assistance. The Act's primary objective is "to use the patent system to promote the utilization of inventions arising from federally supported research or development." *Id.* at § 200.

The Act represents a careful balance between assuring that the public benefits from federally funded inventions and preserving sufficient incentives for a federally funded inventor to commercialize an invention. Funding agreements between the federal government and a non-profit organization must provide that the organization disclose to the federal funding agency each "subject invention," 35 U.S.C. § 202(c)(1), defined as "any invention or discovery which is or may be patentable" "conceived or first actually reduced to practice in the performance of work under a funding agreement." *Id.* at §§ 201(d) & (e). After the required disclosure, however, if none of the narrow circumstances warranting federal assertion of title are present (and if the non-profit organization does not itself elect to retain title to a subject invention), "the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated here-

under." *Id.* at § 202(d).[1] Thus, under the Act, an inventor is permitted to retain patent rights to an invention made while working on a federally funded project, provided that the inventor complies with regulations that assure federal (and employer) interests are protected.

2. Respondent Dr. Gerald Buckberg is the inventor of a cardioplegic solution. (Pet. App. 24a.) "Cardioplegic solutions are chemical solutions used during open-heart surgery and other kinds of stop-heart surgical procedures." (Pet. App. 23a.) The "Buckberg Solution" is a commercially successful product that uses high potassium solutions to stop the heart and low potassium solutions to protect the heart while stopped. (Pet. App. 23a-24a.) Dr. Buckberg invented his solution while conducting research under a National Institutes of Health ("NIH") grant at the University of California. (Pet. App. 26a.)

The Buckberg Solution is protected by U.S. Patent 4,988,515 (the "'515 patent"). (Pet. App. 26a.) The patent lists Dr. Buckberg as the inventor and the Regents of the University of California as the assignees. (*Id.*) Prior to obtaining the patent, Buck-

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[1] Among the regulations promulgated under the Act is 37 C.F.R. § 401.9. Under this regulation, an agency that allows an inventor to retain rights in a subject invention must "impose upon the inventor at least those conditions" set out in six specified portions of § 401.14(a). Among the specified portions is the requirement that the inventor "agrees to execute or to have executed and promptly deliver to the Federal agency all instruments necessary to (i) establish or confirm the rights the Government has throughout the world in those subject inventions . . . ." 37 C.F.R. § 401.14(f)(1).

berg obtained the university's waiver of any patent rights. (Pet. App. 29a.) Buckberg also asked the federal government if he could retain patent rights to the invention. (*Id.*) The federal government – here, acting through the Assistant Secretary of Health, Department of Health and Human Services (also known as the NIH) – replied that

> (1) the invention has been evaluated, and it has been concluded that the Government has insufficient interest in the invention to retain the patent rights; (2) the inventor, Dr. Gerald D. Buckberg, is free to retain and administer the patent rights to the invention in accordance with the requirements of 37 C.F.R. § 401.9; and (3) the inventor shall grant to the Government of the United States a nonexclusive, irrevocable, royalty-free license to use the invention for governmental purposes.

(Pet. App. 71a.) The government asked Buckberg to return a signed copy of the notification, and stated that the government's determination "will become effective upon receipt of the executed copy." (Pet. App. 71a.) For purposes of this opposition, it is assumed that Buckberg neglected to return an executed copy of the government's determination letter or a license.[2]

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[2] Below, the parties agreed that the letter required Buckberg to provide the government with a copy of the executed license. Although not a model of clarity, the letter appears to refer to return of an "executed copy" of the determination. (Pet. App. 71a ("return the fully executed copy" of the determination; "[t]his determination will become effective upon receipt of the

Respondent Central Admixture Pharmacy Services, Inc. ("CAPS") is the exclusive licensee of the Buckberg Solution.

3. CAPS filed this patent infringement suit against respondents Advanced Cardiac Solutions, P.C. and Charles Wall (collectively, "ACS"). Wall is a former employee of CAPS and the founder and director of ACS. The complaint alleges that ACS and Wall are selling cardioplegic solutions that infringe the '515 patent.

The district court ruled that CAPS and Buckberg have standing to bring this lawsuit. ACS argued that Buckberg's (alleged) failure to return an executed copy of the license agreement deprived him of title to the patent and, therefore, invalidated the license he granted to CAPS. But the district court found that Buckberg retained ownership of the patent even assuming Buckberg did not execute a license. Starting with the statute, the district court explained that "the only consequence mentioned in the Act for failing to comply with its requirements is that the federal government will retain the right" – *i.e.*, the option – "to receive title to the invention." (Pet. App. 30a.) Thus, the federal government "may receive title" if disclosure is untimely, 35 U.S.C. § 202(c)(1), and "may receive title" if the contractor

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executed copy").) The record is silent as to whether or not Buckburg returned the executed copy of the determination. In any event, federal regulations required Buckburg to execute a license. 37 C.F.R. § 401.14(f)(1). Although Buckberg provided a declaration that he did execute such a license, the district court ruled that he was bound by a prior admission that he did not do so. (Pet. App. 30a.)

elects not to take title. *Id.* Next, the district court observed that the "Federal Circuit has confirmed that the phrase 'the Federal Government may receive title' means that the federal government has discretion to determine whether to take title to the invention." (Pet. App. 31a.) In addition to text and case law, the district court explained that its "conclusion furthers the purposes of the Bayh-Dole Act by interpreting the law to preserve the government's rights to inventions created through government funding and also by declining to interpret the law to provide additional defenses to alleged patent infringers." (Pet. App. 32a.) Here, because ACS "failed to present any evidence that the NIH has taken title to the '515 patent," the district court denied ACS's motion to dismiss for lack of standing.

ACS appealed to the Federal Circuit. The Federal Circuit affirmed, agreeing with the district court's interpretation of text, case law and policy. The court explained that Federal Circuit law "holds that a Bayh-Dole violation grants the government *discretionary* authority to take title." (Pet. App. 7a.) "When a violation occurs, the government can choose to take action; thus, title to the patent may be voidable." (Pet. App. 8a.) But, the court continued, "it is not void: title remains with the named inventors or their assignees." (*Id.*) "Absent any action by NIH, Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid." (*Id.*) Because the "two plaintiffs together own all present rights to the '515 patent," the plaintiffs have "standing to bring the action." (*Id.*)

ACS petitions.[3]

THE DECISION BELOW IS CORRECT AND PRESENTS NO GROUNDS WARRANTING FURTHER REVIEW

I. THE DECISION BELOW IS CORRECT

As the district court and the court of appeals both concluded, the relevant text, case law and policy concerns establish beyond question that respondent Buckberg has standing to bring this suit. Under the Bayh-Dole Act, if none of the narrow circumstances warranting federal assertion of title are present "the Federal agency may consider and after consultation with the contractor grant requests for retention of rights by the inventor subject to the provisions of this Act and regulations promulgated hereunder." 35 U.S.C. § 202(d). Here, the NIH granted Buckburg the right to retain rights to his invention subject to the provisions of the Act and relevant regulations. One such regulation required him to submit an executed copy of the government license. But even assuming he failed to do so, nothing in the Act or the regulation specifies that the consequences of failing to do is that the NIH's decision to allow him to retain rights is automatically undone. (*See* Pet. App. 30a ("this consequence" – *i.e.*, that "Buckberg never obtained title" – "is nowhere mentioned in the Act").) To the contrary, failure to comply with the Act's re-

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[3] Although the district court found that ACS infringed the patent, the Federal Circuit reversed and remanded the case for further proceedings. (Pet. App. 17a.) Thereafter, the district court dismissed the case under the mistaken view that CAPS had withdrawn certain claims. CAPS has filed a notice of appeal. Fed. Cir. No. 2007-1575.

quirements simply provides the government with the on-going option of asserting title.

Campbell Plastics Engineering & Manufacturing, Inc. v. Brownlee, 389 F.3d 1243 (Fed. Cir. 2004), is squarely on point. In that case, a federal contractor failed to disclose an invention to the federal government. The court held that this non-compliance with requirements of Bayh-Dole regulations meant that "the government may take title to the invention." 389 F.3d at 1249. *See also id.* at 1250 ("may obtain title"). In other words, the contractor's failure to comply with the regulation "afforded the government the opportunity to take title to its patent." *Id.* at 1249 (emphasis added). As the Federal Circuit explained, "the decision to demand title is a discretionary matter." *Id.* at 1250. The regulation "vests discretion in the government in determining whether to invoke forfeiture when an invention has not been correctly disclosed to it." *Id.* As the Federal Circuit below summarized, "[c]ritically, *Campbell Plastics* holds that a Bayh-Dole violation grants the government *discretionary* authority to take title." (Pet. App. 7a.)[4]

This case is the mirror image of *Campbell Plastics*. There, the government elected to assert its right to take title; in this case, the federal government has never sought to invoke its right to take ti-

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[4] To the extent *TM Patents, L.P. v. International Business Machines*, 121 F. Supp. 2d 349 (S.D.N.Y. 2000), is at odds with *Campbell Plastics*, it "is contrary to the language of the Act, contrary to the binding authority of the Federal Circuit, and unsupported by the authority to which it cites." (Pet. App. 31a n.6.)

tle. As the court of appeals accurately stated, "NIH has shown no interest in pursuing this matter." (Pet. App. 8a.) But the statutory interpretation set out in *Campbell Plastics* governs both instances. In either case, the government has the option of asserting title, but nothing compels it to do so. Under *Campbell Plastics*, NIH's decision not to exercise its discretion means that "Dr. Buckberg retains title to the patent and his exclusive license to CAPS is valid." (Pet. App. 8a.)

Furthermore, the fundamental policy concerns of the Bayh-Dole Act are advanced by the decisions below. As explained above, the Act is a careful balance between preserving government benefits from federally funded inventions and providing incentives for commercialization of such inventions. All government interests are protected by a rule that grants the government discretion to assert title. If a government interest is implicated, the government need only assert its rights. But absent such an assertion, granting title to the inventor permits the inventor to commercialize the subject invention as anticipated by the Act.

In contrast, the rule advocated by petitioners would unfairly punish an inventor with no gain to the federal government. Under either view of the law, the government gets title or a license to the invention when it wants one, either automatically (petitioners' view) or when it requests one (per the courts below). But only the petitioners' view would convert government inaction into authority for a patent infringer to practice the patented intention without a license from the inventor. (Pet. 19 ("government inaction is not a ground for upholding a

valid assignment but rather precludes the existence of a valid assignment").) Nothing in the Bayh-Dole Act suggests that it was intended to allow non-federal entities to practice an invention patented by others pursuant to a federal grant.

II. THERE IS NO BASIS FOR FURTHER REVIEW

1. The decision below is fully consistent with this Court's decision in *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24 (1923). In *Crown*, the patent owner retained the "right to make, use and vend, but [gave] to many different individuals the right to sue certain named infringers." 261 U.S. at 37. The Court held that "the attempted assignment" "carried no part of the title to the patent." *Id.* at 39. As a result, the case did not arise under the patent laws and thus the district court could not base jurisdiction on its patent law authority. As both parties were "citizens of the same [s]tate," *id.* at 33, there was no federal district court jurisdiction. Thus, the assignee was required to bring a state-law contract suit in state court.

Petitioners cite *Crown* for the proposition that "compliance with the conditions specified by the Bayh-Dole Act and its implementing regulations are conditions precedent to an acquisition of title under the Act." (Pet. 13.) But *Crown* does not involve the Bayh-Dole Act (which was enacted nearly fifty years after this Court decided *Crown*), nor does this case raise the scope of "arising under the patent laws" jurisdiction.[5] More fundamentally, Buckberg's right to

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[5] Despite petitioners' persistent attempt to cast this case as presenting a question regarding Article III jurisdiction, the

title in his own invention bears no resemblance to that of the plaintiff in *Crown*, a plaintiff who had only been assigned the right to sue a particular infringer. Nothing in *Crown* forecloses the Federal Circuit's decision that, absent an assertion of right by the government, failure to comply with a Bayh-Dole regulation renders a title in a patent voidable but not void.

2. The decision below is fully consistent with decisions from other circuits. In an effort to show circuit conflicts, petitioners cite (at 17-19) three circuit court decisions, *Havana Club Holdings, S.A. v. Galleon, S.A.*, 203 F.3d 116 (2d Cir. 2000), *Nursing Center of Buckingham & Hampden, Inc. v. Shalala*, 990 F.2d 645 (D.C. Cir. 1993), and *Southern Research Institute v. Griffin Corp.*, 938 F.2d 1249, 1254 (11th Cir. 1991). There is no tension between these decisions and the decision below, let alone a conflict requiring this Court's intervention.[6]

According to petitioners, *Havana Club* and *Nursing Center* hold that "restrictions on the acquisition of ownership rights requiring agency approval or other approvals required as conditions precedent

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only Article III issue they identify – that a party with no rights under a patent lacks standing to assert a patent-infringement claim – is not in dispute.

[6] Petitioner claims that "the Federal Circuit abrogated an agency determination which was committed to the discretion of the agency." (Pet. 18-19.) Here, however, the relevant agency has elected *not* to assert title in the patent. Accordingly, the decision below does not in the least intrude upon agency discretion. To the contrary, the decision below holds that the relevant federal agency at all times had and continues to have the option to assert - or not to assert - title in this patent.

under statutes precluded the acquisition of such rights where such approval is not obtained." (Pet. 18.) But even if these cases so hold, that proposition has no bearing here. In this case, the relevant law provides Buckberg with title to his patent subject to certain conditions. The question is whether the government will permit an inventor to "retain" rights in the invention. 35 U.S.C. § 202. But in the cases cited by petitioners, title never passed to the plaintiff because certain pre-conditions were not met. *Cf. Havana Club*, 203 F.3d at 121 (Cuban embargo expressly prohibits trademark assignment to Cuban company unless exception); *Nursing Center*, 990 F.2d at 648 (where merger agreement contains multiple express "conditions precedent" that had not yet been complete, not unreasonable for agency to deem merger incomplete for tax purposes). *Havana Club* and *Nursing Center* involve the vesting of title not, as here, the circumstances in which an inventor is not permitted to retain title to an invention. General principles from a Medicare reimbursement case and a Lanham Act case cannot create a meaningful circuit conflict with this Bayh-Dole Act dispute.

Although *Southern Research* is at least a patent case, its holding also has nothing to do with this case. There, the government granted a license but failed to comply with the public notice provisions of the Bayh-Dole Act. 938 F.2d at 1254; *see* 35 U.S.C. § 207(a). A competitor of the licensee argued that the government lacked title to the patent because the government failed to provide proper notice. The competitor, however, had actual notice of the licensing opportunity. As a result, the court ruled that the competitor should have pursued any complaints

through the available administrative processes. 938 F.2d at 1253 (citing 35 U.S.C. §§ 207 and 209). This holding on exhaustion has no bearing here.

Indeed, if anything, *Southern Research* supports the view of respondents that errors in compliance with a notice provision of the Bayh-Dole Act do not automatically void title in the subject patent. In *Southern Research*, the court was well aware that the government had issued a license without complying with the requirements of the Act. Yet, that error did not cause the court to invalidate either the license or underlying patent. So too, in this case, any procedural error regarding the government's license is no basis for stripping Dr. Buckberg of the rights to his invention.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted,

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